

### **REMARKS**

Claims 1 – 98, 133, 134, and 136 – 168 remain pending in the present application. However, claims 1 – 3, 5 – 7, 11 – 17, 50 – 52, 54 – 56 and 60 – 66 have been rejected, 4, 8 – 10, 18 – 49, 53, 57 – 59, 67 – 98, 133, 134, and 136 – 168 have been withdrawn pursuant to a restriction requirement, claims 1, 16 and 50 are hereby amended and claims 99 – 132 and 135 have been previously canceled. Applicant respectfully requests reconsideration by the Examiner of the pending claims in light of the following remarks.

The Applicant thanks the Examiner for extending the courtesy of an interview with John F. Dolan and Dr. David Masters on August 7, 2008 to discuss the above identified application and the reconsideration of the pending claims thereof. A Statement of Substance of Interview for the interview is herein enclosed.

#### **Claim Rejections based on 35 USC § 112, second paragraph**

The Examiner has rejected claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention by failing to end the claim with a period. The Applicant has amended claim 16 by adding a “.” to the end of this claim.

#### **Claim Rejections based on 35 USC § 103**

The Examiner has rejected claims 1 – 3, 5 – 7, 11 – 17, 50 – 52, 54 – 56, and 60 – 66 under 35 U.S.C. §103(a) as being unpatentable over Dinh et al. (U.S. Patent No. 5,510,077) in view of Greatbatch (U.S. Patent No. 4,405,311). In response, Applicants respectfully traverse the above-mentioned rejections under 35 U.S.C. §103(a) and respectfully request reconsideration by the Examiner in view of the following remarks.

As is well established, the Examiner bears the initial burden in establishing a prima facie case of obviousness when rejecting claims under 35 U.S.C. §103. In re Piasecki, 745 F.2d 1468, 223 USPQ 758 (Fed. Cir. 1985); In re Reuter, 651 F.2d 751, 210 USPQ 249 (CCPA 1981). If the Examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of non-obviousness.

To properly establish a prima facie case of obviousness, MPEP § 706.02(j) identifies three basic criteria that must be met. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. Prior art under 35 U.S.C. §103 is the same as prior art under 35 U.S.C. §102. MPEP § 2141.01. Additionally, there must be a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

With regards to the rejection of the claims 1 – 3, 5 – 7, 11 – 17, 50 – 52, 54 – 56, and 60 – 66 under 35 U.S.C. §103(a) as being unpatentable over Dinh in view of Greatbatch, the Applicant respectfully traverses the Examiners rejection due to the premise that Dinh in view of Greatbatch fails to disclose all of the limitations of the amended claims above. For example, neither Dinh or Greatbatch disclose a current release drug delivery device or an electromatrix device that includes the limitations of 1) an intermediate material, the cohesive body, having a solvent content of about 20% to 80% prior to compression; 2) the cohesive body compressed at a pressure of about 100 psi to 100,000 psi to remove bulk biocompatible solvent and generate additional intermolecular and intramolecular forces between one or more of the protein materials, conductive materials, active agents and solvents; and 3) the current released drug delivery device having a solvent content of about 10% to 60%.

As previously expressed in prior office actions, it is important that the protein and solvent molecules of the intermediate material (i.e. the cohesive body) be allowed to closely interact through physical bonds and molecular forces, such as non-covalent bonding and electrostatic interactions (not substantially through chemical bonds, such as covalent bonds, as found in gels and/or crosslinked matrices), but remain substantially unset and mobile. Such interaction and the unset and mobile characteristics found among the protein and solvent molecules allows this protein-solvent material to be cohesive, formable and compressible so bulk water can be reduced during compression, thereby forming the current release drug delivery device and/or the electromatrix of the present invention. It has been found by the Applicant that unless the protein/solvent composition has reached this well-defined cohesive, formable and compressible state (i.e. the cohesive body), wherein the solvent content is sufficient to facilitate mobility and the protein and solvent molecules are still mobile within the cohesive body, a current release drug delivery device or electromatrix material of the present invention cannot be formed upon compression.

Moreover, the protein molecules' ability to remain mobile in a properly solvated environment, as found in the cohesive body, and to re-organize is necessary for additional binding among the protein and solvent molecules upon compression. Generally, the proper compression of a cohesive body alters protein molecule conformation and their relative position within the cohesive body, thereby bringing the protein molecules and their binding sites closer together with each other and the solvent molecules to form additional bonds that would not be formed but for the mobile characteristics maintained by the protein in the cohesive body. These mobile characteristics are not found in crosslinked matrices, such as the fibrin material of Dinh, which is formed by crosslinking fibrinogen and thrombin. Furthermore, in the present invention,

the proper amount of compression at a pressure of about 100 psi to about 100,000 psi allows the conformation of the protein to alter, thereby opening additional protein binding sites for interaction with additional solvent molecules, which transforms the cohesive body into a much stronger structure. Such interaction through compression is not possible with a crosslinked fixed material like fibrin. Hence a compressed current release drug delivery device or an electromatrix product of the present invention could not be formed by using the teachings of Dinh and/or Greatbatch.

Furthermore, as previously suggested, the Dinh reference does not disclose or suggest the claimed intermediate material, the cohesive body. As previously mentioned, the cohesive body having a solvent content of about 20% to 80% prior to compression is necessary to formulate the compressed current release drug delivery devices and electromatrix products of the present invention. Without a cohesive body having the proper solvent content, thereby providing the proper proportions and positioning of protein and solvent molecules, the compression will not produce the desired drug delivery device or electromatrix material. For example, too much solvent will cause the composition to be too much like a liquid, thereby preventing the material from being cohesive, i.e. the composition will not substantially stick to itself. Alternatively, too little solvent will cause the composition to crack, shatter, break or otherwise lack cohesiveness upon efforts to form the cohesive body. Compression of a crosslinked material, such as the fibrin material of Dinh, will tend to cause the composition to crack, shatter, break or otherwise lack cohesiveness because the fibrin material is already in a crosslinked/fixed state.

Finally, the cited references in the office action do not disclose a current release drug delivery device or electromatrix device that includes a final solvent content of about 10% to

about 60%. Such an illustration indicates that compression of the intermediate material (i.e. the cohesive body) has substantially reduced and/or eliminated the bulk solvent and has forced additional interaction between the remaining protein and solvent molecules to form a structurally enhanced material. For example, it has been found by the inventors that tubes produced using the processes of the present invention, similar to the tubes illustrated in Figure 9, have been able to repeatably withstand back pressures in excess of 200 mm of Hg without damaging the tubes. In view of the previously submitted paragraphs, it is evident that the cited references fail to disclose or suggest all the limitations of the claims of the present application. Since the limitations of the present claims are not found in the teaching of the materials disclosed by Dinh or Greatbatch, Applicant respectfully requests that the rejection under 103(a) be withdrawn and that the pending claims be allowed.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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